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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/822,682

04/13/2004

Eric Berreklouw

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2986

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EXAMINER

BLANCO, JAVIER G

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

10/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/822,682	Applicant(s) BERREKLOUW, ERIC	
	Examiner Javier G. Blanco	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 72-83,85-90 and 122-124 is/are pending in the application.
- 4a) Of the above claim(s) 76,78-83,85-87,89 and 90 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 72-75,77,88 and 122-124 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 21, 2007 has been entered.

Response to Amendment

2. Applicant's amendment of claims 72, 73, and 88 in the reply filed on August 21, 2007 is acknowledged.
3. Applicant's cancellation of claims 92-121 in the reply filed on August 21, 2007 is acknowledged.
4. Applicant's addition of claims 122-124 in the reply filed on August 21, 2007 is acknowledged.

Claim Objections

5. Claims 72, 73, and 88 are objected to because of the following informalities:
 - a. Regarding claim 72, please (i) substitute "said valve prosthesis, inside the lumen" (see lines 6-7) with --said valve prosthesis, inside the lumen-- (in other words, remove the comma between "prosthesis" and "inside"), and (ii) substitute "a fixing position" (see line 20) with --a fixing the inserted position--. It is noted that in claim 72 the Applicant is using "fixing position" and

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“inserted position” interchangeably. The “insertion position” is shown in Figure 15A, and the “inserted position” is shown in Figure 15B. Appropriate correction is required.

b. Regarding claim 73, please substitute “the fixing position” (see line 10) with ~~--the fixing the~~ inserted position--. It is noted that in claim 72 the Applicant is using “fixing position” and “inserted position” interchangeably. The “insertion position” is shown in Figure 15A, and the “inserted position” is shown in Figure 15B. Appropriate correction is required.

c. Regarding claim 88, please (i) substitute “from an initial position into the insertion position” (see lines 3-4) with ~~--from an initial~~ the insertion position into the ~~insertion~~ inserted position--, (ii) substitute “said insertion position” with ~~--said insertion~~ inserted position--, and (iii) substitute “the fixing position” (see line 7) with ~~--the fixing position~~ its initial position when in the insertion position--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 72-75, 77, 88, and 122-124 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Shiley (US 3,686,740 A; cited in Applicant's IDS).

Referring to Figures 5-7, 9, and 25-30, Shiley discloses a prosthesis fixing device comprising a tubular element (**first interpretation:** outer ring 11, outer ring 111; **second interpretation:** inner ring 12, inner ring 112; **third interpretation:** outer ring 11 + inner ring 12; **fourth interpretation:** outer ring 111 + inner ring 112) providing a lumen (**first interpretation:** lumen formed between the outer ring and the inner ring; **second interpretation:** lumen formed by outer ring; **third interpretation:** lumen formed by inner ring) therethrough and *intended to lie*, when the prosthesis fixing device is in an inserted position, with an outside in contact (directly or indirectly) with a wall part of the circulatory system and capable of accommodating a valve prosthesis (e.g., valve 15) inside the lumen of said tubular element, the tubular element having pins (pins 13) distributed around the periphery of said tubular element, said pins having pointed ends, wherein each pin is arranged on an arm which arm, via a fold or bend line, is attached by one end to the tubular element, wherein the arms and pins are capable of moving, by swinging about the fold or bend line, from an insertion position (e.g., Figure 5), in which they are ESSENTIALLY located inside the lumen of the tubular element, to a fixing position (e.g., Figure 6) in which at least the pins project from the outside of the tubular element. Each of wire suture pins 13 comprises a basal end 43, a body portion 50, and a distal end 49. The tubular element is provided with slit-shaped radial passages (radial slots 35, annulus 52, and/or apertures 41) located alongside the pins in the radial direction, which slit-shaped radial passages extend in the longitudinal direction (e.g., pointing in the same direction) of the arms. Regarding the term “integral”, it is broadly interpreted as “unitary”. “Integral” is not the same as “monolithic”.

Regarding the “bend line”, both of Figures 5 and 6 clearly show the arms and pins as movable about a bend line. It is noted that the pins are not straight, but have a curve/bend profile. The motion/movement depicted in Figures 5 and 6 could be broadly considered “by swinging”. Additionally, the swinging motion could also develop at the bend line between distal end 49 and body portion 50 (see Figure 7).

Note: Regarding the statements of intended use and other functional statements (e.g., intended to lie; to accommodate; permits swinging; etc.), they do not impose any structural limitations on the claims distinguishable over the device of Shiley ‘740, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

8. Claims 72-75, 77, 88, and 122-124 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Stevens (US 5,370,685 A; cited in Applicant’s IDS).

Referring to Figures 9-15, Stevens discloses a prosthesis fixing device comprising a tubular element (annular ring 85) providing a lumen (lumen of ring 85) therethrough and *intended to lie*, when the prosthesis fixing device is in an inserted position, with an outside in

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contact (directly or indirectly) with a wall part of the circulatory system and capable of accommodating a valve prosthesis (see Figure 11) inside the lumen of said tubular element, the tubular element having pins (mounting pins 90) distributed around the periphery of said tubular element, said pins having pointed ends (Figures 13a-15b), wherein each pin is arranged on an arm (**first interpretation:** main body portion of mounting pins 90; **second interpretation:** half the body portion of mounting pin 90) which arm, via a fold or bend line (Figures 13b, 14b, 15a, and 15b), is attached by one end to the tubular element, wherein the arms and pins are capable of moving, by swinging about the fold or bend line (compare Figure 10 to Figure 11; compare Figure 13b to Figure 14b; compare Figure 15a to Figure 15b; see column 9, lines 35-47), from an insertion position, in which they are ESSENTIALLY located inside the lumen of the tubular element (compare Figure 10 to Figure 11; compare Figure 13b to Figure 14b; compare Figure 15a to Figure 15b; see column 9, lines 35-47), to a fixing position in which at least the pins project from the outside of the tubular element. The tubular element is provided with slit-shaped radial passages (see Figure 13a and Figure 14a) located alongside the pins in the radial direction, which slit-shaped radial passages extend in the longitudinal direction (e.g., pointing in the same direction) of the arms. Regarding the term “integral”, it is broadly interpreted as “unitary”.

“Integral” is not the same as “monolithic”.

Note: Regarding the statements of intended use and other functional statements (e.g., intended to lie; to accommodate; permits swinging; etc.), they do not impose any structural limitations on the claims distinguishable over the device of Shiley '740, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in

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terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

9. Claims 72, 73, 88, and 122-124 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Magovern et al. (US 6,106,550 A).

Referring to Figures 1-6, Magovern et al. disclose a prosthesis fixing device comprising a tubular element (annular ring 2) providing a lumen (lumen 8) therethrough and *intended to lie*, when the prosthesis fixing device is in an inserted position, with an outside in contact (directly or indirectly) with a wall part of the circulatory system and capable of accommodating a valve prosthesis (valve 26) inside the lumen of said tubular element, the tubular element having pins (pins 20) distributed around the periphery of said tubular element, said pins having pointed ends (ends 22), wherein each pin is arranged on an arm (**first interpretation:** end 24; **second interpretation:** basal half of pin 20) which arm, via a fold or bend line, is attached by one end to the tubular element, wherein the arms and pins are capable of moving, by swinging about the fold or bend line, from an insertion position, in which they are ESSENTIALLY located inside the lumen of the tubular element (Figure 3; column 3, lines 52-56), to a fixing position (Figure 6) in which at least the pins project from the outside of the tubular element. The tubular element is provided with slit-shaped radial passages (channels/passages 18) located alongside the pins in the

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radial direction, which slit-shaped radial passages extend in the longitudinal direction (e.g., pointing in the same direction) of the arms. Regarding the term “integral”, it is broadly interpreted as “unitary”. “Integral” is not the same as “monolithic”.

Regarding the “bend line”, both of Figures 3 and 6 clearly show the arms and pins as movable about a bend line. It is noted that the pins are not straight, but have a curve/bend profile, and could be made from shape memory material (see column 3, lines 58-65). The motion/movement depicted in Figures 3 and 6 could be broadly considered “by swinging”.

Note: Regarding the statements of intended use and other functional statements (e.g., intended to lie; to accommodate; permits swinging; etc.), they do not impose any structural limitations on the claims distinguishable over the device of Shiley '740, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Response to Arguments

10. With regards to the 102(b) rejection based on Shiley (US 3,686,740 A; cited in Applicant's IDS), Applicant's arguments filed March 6, 2007 have been fully considered but they are not persuasive.

a. Regarding claim 72, the Applicant argues that Shiley does not disclose: "*wherein the arms and pins are movable, by swinging about the bend line, from an insertion position, in which they are ESSENTIALLY located inside the lumen of the tubular element*". The Examiner respectfully disagrees. Under the several "lumen" interpretation offered by the Examiner (see 102(b) rejection above), pins 13 are essentially located inside the lumen of the tubular element in the insertion position.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-7:00 p.m.), first Friday of the bi-week off.

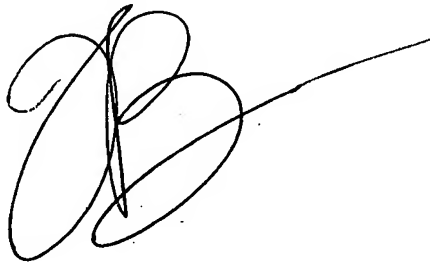
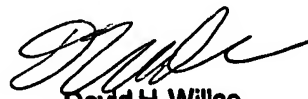
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 24, 2007

Javier G. Blanco

A large, stylized handwritten signature in black ink, consisting of a large 'B' followed by a long horizontal stroke.A handwritten signature in black ink, appearing to read 'D. Willse' with a stylized flourish.

David H. Willse
Primary Examiner